



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland, Florida 32751

Telephone: 407-475-4700  
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-39

March 13, 2000

Gerald L. Pack, President  
Miss Becky's Seafood d.b.a.  
Safe Harbor Seafood, Inc.  
4371 Ocean Street  
Mayport, Florida 32233

Dear Mr. Pack:

We completed an inspection your seafood processing plant on January 10, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find the Act and these regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with 21 CFR 123.6(c)(7). However, you did not have monitoring records to document the examination of labels at the weigh/pack/label critical control point specified in your HACCP plan for shrimp to control the food safety hazard of sulfites. This deviation was previously brought to your attention in our letter of July 20, 1999.

In addition, you did not have monitoring records (lot-by-lot certificates) specified in your HACCP plan for various species of fin fish to document the receipt of certificates at the receiving critical control point to control the food safety hazards of natural toxins (ciguatera), environmental chemicals/pesticide contaminants, and aquaculture drugs.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the GMP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in cursive script, appearing to read "Marie A. Urban".

Marie A. Urban  
Acting Director  
Florida District

bcc:

HFR-SE240/JEW/LGL JKT/WL FILE JKT

HFR-SE250/DIB/EI JKT

-RP

MIA-RP/MAL/KMS

HFA-224

HFI-35 (PURGED)

HFC-210

HFS-607

DR. FRUIN, W/483

CHIEF, BUREAU OF FOOD & MEAT INSPECTION

FDACS/DIVISION OF FOOD SAFETY

3125 CONNER BLVD.

TALLAHASSEE, FL 32399-1650

CBA:6652

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DFT:03/13/2000

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